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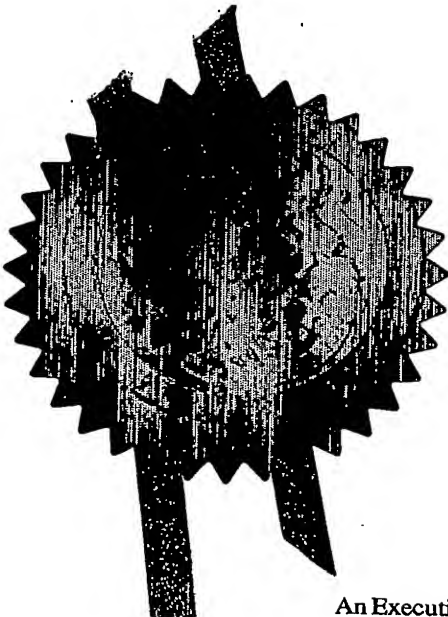
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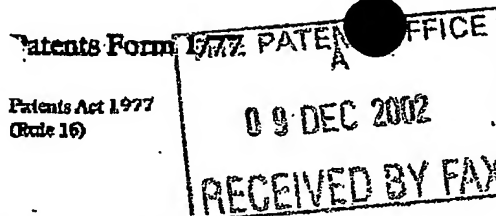
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09DEC02 E769631-1 000318
P01/7700 0.00-0228649.0

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(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

KJL/CT/P5127

2. Patent application number

(The Patent Office will fill in this part)

0228649.0

09 DEC 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Zi Medical PLC
Unit 4
St Asaph Business Park
St Asaph
Denbighshire LL17 0LJ
United Kingdom

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

08523862001

4. Title of the invention

An improved Infusion Apparatus

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

ROYSTONS,
Tower Building,
Water Street,
Liverpool, L3 1BA
Merseyside.

Patents ADP number (if you know it)

1438001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.

See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 7

Claim(s) -

Abstract -

Drawing(s) 4 *only 8*

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

ROYSTONS

09/12/02

12. Name and daytime telephone number of person to contact in the United Kingdom

K.J. Lees - 0151-236 5147/1417

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Title: An improved Infusion Apparatus.

DESCRIPTION

The present invention relates to an improved infusion apparatus, in particular in relation to the giving set of an infusion apparatus.

5 Healthcare workers are at risk from needlestick injuries from the use of needles and sharps. Not only are such injuries painful but these exposures can lead to the contraction of serious infections, such as hepatitis B, hepatitis C and Human Immunodeficiency Virus. This has led to a movement towards the replacement of a large number of needle devices by safer needleless systems. The majority of
10 medications that were previously administered to a patient via the needle of a syringe may now be administered using a needle-free device. A large number of such devices of varying design are currently on the market. Generally medication is loaded into the syringe directly, without the requirement for a needle, by providing a luer adapter on the container containing the medication. The container is opened by applying
15 pressure to a spring provided within the luer using the syringe tip. As soon as the syringe is removed from the luer, the opening is biased shut. The medication may then be administered to a patient by means of, for example an injector attached to the syringe that has substantially smaller hole than a needle.

Intravenous drip bags, for example for administering saline solution to a
20 patient, often require medication, such as antibiotics, to be added to the bag. Currently, this is achieved by inserting the needle of a syringe through a self-sealable rubber bung provided at the base of the bag. Accordingly, it is still possible for healthcare staff to suffer needlestick injuries as a result of having to introduce fluid medicaments into an IV bag using a needle and syringe. This is clearly undesirable.

It is an object of the present invention to provide a novel giving set for an infusion apparatus that aims to overcome the abovementioned drawbacks.

Accordingly, a first aspect of the present invention provides a giving set cap for providing fluid communication between two vessels, the cap comprising a delivery tube having a main channel for delivering fluid from a first vessel to a second vessel and a subsidiary channel for the delivery of a different material to said first or second vessel characterised in that the cap includes one or both of the following features:

- (a) an inlet for delivering fluid from said first or second vessel through the main channel, the inlet being spaced at a sufficient distance from an outlet of the subsidiary channel to allow mixing of the different material with said fluid prior to delivery to said other vessel; and
- (b) an inlet of the subsidiary channel being adapted to receive a needleless syringe.

A second aspect of the present invention provides a giving set comprising a drip chamber attached to a line with a giving set cap as hereinbefore described.

A third aspect of the present invention provides an infusion apparatus comprising a IV bag or container, a giving set cap connecting said bag/container to a drip chamber having a line, characterised in that the giving set cap comprises a delivery tube having a main channel for delivering fluid from the bag/container to the chamber and a subsidiary channel for the delivery of a different material to said bag/container, the cap including one or both of the following features:

- (a) an inlet for delivering fluid from the bag/container through the main channel to the chamber, the inlet being spaced at a sufficient distance

from an outlet of the subsidiary channel to allow mixing of the different material with said fluid prior to delivery to the chamber; and

- (b) an inlet of the subsidiary channel is adapted to receive a needleless syringe.

5 Preferably, the giving set cap further comprises connector means, the connector means allowing attachment of the cap to a giving set chamber. More preferably, the cap also comprises piercing means for attachment to an IV bag or container. Preferably, one end of the delivery tube is tapered to provide said piercing means. The main channel of the delivery tube preferably extends through said
10 connector means.

It is preferable for the at least one inlet of the main channel to be provided in the part of the delivery tube that extends into the IV bag or container. Preferably, at least one outlet for the delivery tube is provided in the connector means. At least one inlet for the subsidiary channel is preferably provided in the connector means with at
15 least one outlet being provided in the part of the delivery tube that extends into the IV bag or container, more preferably, being in or close to said piercing means.

Preferably, the giving set cap is provided with an inlet for delivering fluid from said first or second vessel through the main channel, the inlet being spaced at a sufficient distance from an outlet of the subsidiary channel to allow mixing of the
20 different material with said fluid prior to delivery to said other vessel and is provided with a subsidiary channel that has an inlet that is adapted to receive a needleless-syringe. In this manner, fluid can be inserted into the bag via the inlet of the subsidiary channel by means of a needleless syringe, enters the bag through an outlet of the subsidiary channel that is spaced at a sufficient distance from the inlet of the

main channel to allow mixing of the different fluids prior to delivery to the chamber via the main channel.

Preferably, the outlet of the subsidiary channel is spaced at least 10mm from the inlet of the main channel, more preferably still, the outlet is spaced at least 20mm from the inlet of the main channel, especially at least 25mm.

Preferably, the end of the piercing means is tapered but rounded. Preferably, the main channel is provided with at least two, preferably three inlets. Preferably, the subsidiary channel is provided with a single outlet.

The inlet of the subsidiary channel may also act as an air inlet to allow air to enter the bag via the giving cap. Preferably, the inlet is provided with a detachable cover. The inlet is preferably provided in one side of the connector means, preferably with the subsidiary channel extending up one side of the delivery tube.

The connector means may be, for example, provided with internal threads for attachment to the drip chamber of a giving set. However, any other suitable means may be provided to allow attachment to the drip chamber via the connector means. Preferably, the connector means is cylindrical member having the main channel extending through the centre thereof.

For a better understanding of the present invention and to show more clearly how it may be carried into effect reference will now be made by way of example only to the accompanying drawings in which:

Figure 1 is a schematic diagram of a conventional infusion apparatus;

Figure 2 is one side view of a conventional giving set cap used in the apparatus of Figure 1;

Figure 3 is the other side view of the giving set cap shown in Figure 2;

Figure 4 is one side view of a giving set cap according to one embodiment of the present invention;

Figure 5 is the other side view of the giving set cap shown in Figure 4; and

Figure 6 is a schematic diagram of the giving set cap of Figures 4 and 5

5 attached to a conventional IV bag.

Figures 1 to 3 of the accompanying drawings illustrate a conventional infusion apparatus, including the manner in which a solution of medication, such as an antibiotic, is introduced into an IV bag. The bag 2 is mounted on a stand 1 and the base of the bag is provided with a connector 4 and an outlet 6 sealed by means of a
10 rubber bung 8. If a medicament is to be introduced into the bag, this is administered using a syringe with a needle 5 by inserting the needle through the rubber bung 8. The infusion line 16 is attached to the bag via a giving set cap 10. The giving set cap has a spike 12 that, in use, extends through the connector 4, and a luer 11 at the opposite end thereof that is secured to a drip chamber 14 that terminates in a line 16
15 that extends to a patient. A ball valve 18 enables the rate of flow of fluid through the line 16 to be adjusted. The giving set cap, drip chamber, line and valve makes up a giving set.

The spike 12 of the giving set cap 10 is provided with a central main channel 18 which terminates in three openings 20a, 20b, 20c on three sides of the spike
20 towards the free end thereof, the opposite end of the channel extending past the end of the luer (see Figure 3). Additionally, a second discrete channel 21 extends up one side of the spike to an opening 22 closer to the free end of the spike than the openings 20a, 20b, 20c (see Figure 2). This channel extends from an air inlet 23 provided on one side of the luer of the cap that is normally provided with a cover (not shown). In

this manner, fluid from the bag is able to flow through the openings 20a, 20b, 20c through the channel 18 and into the chamber to be administered to the patient. If the bag is of a rigid material, air is allowed to enter into the bag by removing the cover 25 from the cap to enable air to enter the inlet 23 flow up the channel 21 out of the opening 22 and into the bag, thereby preventing a vacuum forming above the fluid in the bag.

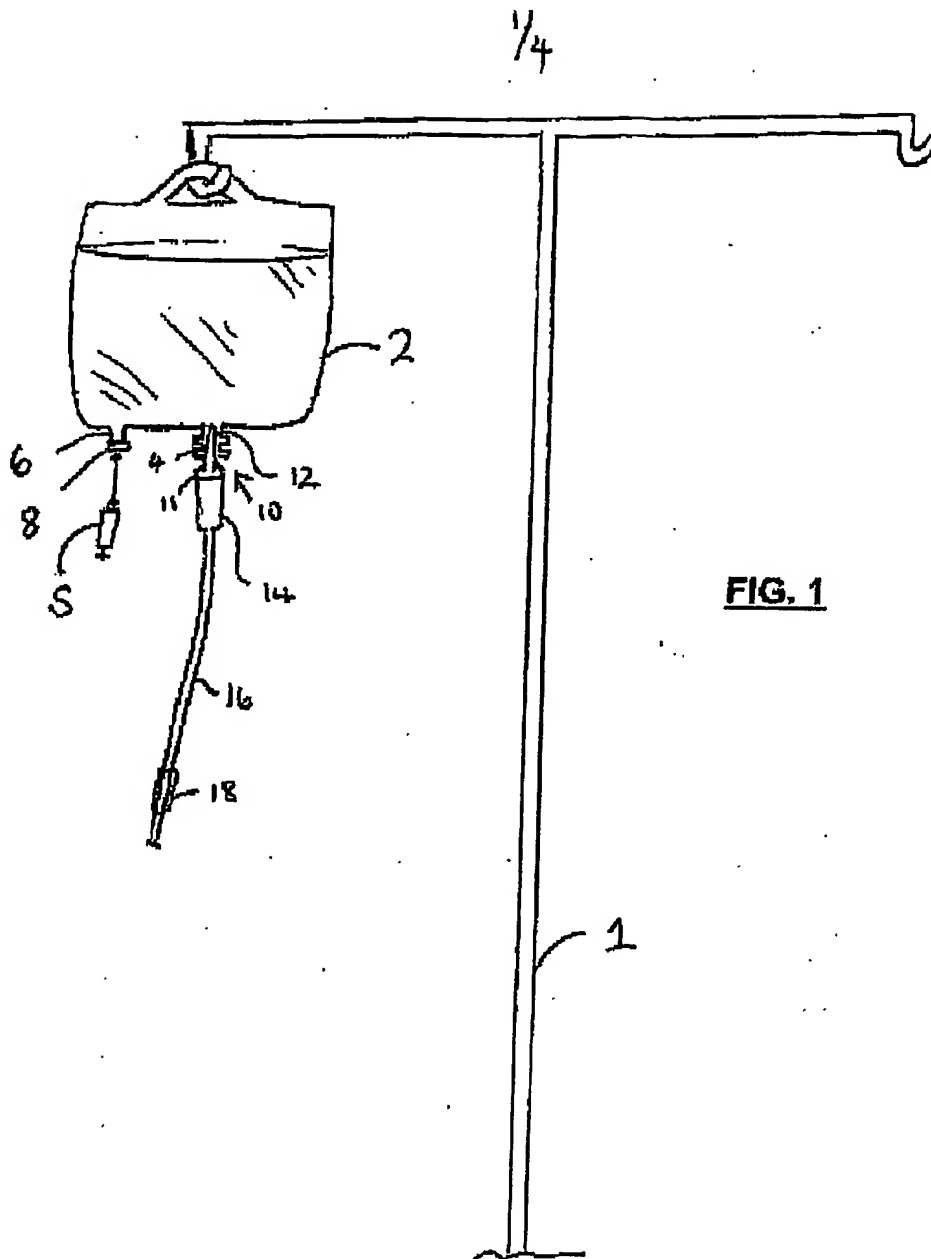
The present invention provides a modified giving set cap 40 to enable medication to be inserted into the bag through the cap itself via a needleless syringe, thereby removing the need for the separate outlet and the use of a needle. Figures 4 and 5 of the accompanying drawings illustrate one embodiment of a giving set cap according to the present invention. The general construction of the cap is the same as hereinbefore described, i.e. having a luer end 42 for connection to a chamber and a spike 44 that may be inserted into the bag. However, the length of the spike of the cap is increased such that it is able to extend well into the body of the bag 2. The channel that extends from the air inlet 45 again extends to an opening 46 at or near to the free end of the spike but the openings 48 for the main channel 50 are distanced approximately 25mm from the opening 46. Additionally, the inlet 45 is adapted to receive a needleless syringe and is provided with a cover (not shown). The head of the spike may be rounded so as to prevent puncturing of the bag. It is to be appreciated that the inlet may be adapted in any conventional manner depending upon the type of needleless syringe to be used with the giving set.

In this manner, a conventional needleless syringe S may be used to introduce fluid into a bag 2 by engagement of the syringe with the adapted inlet, see Figure 6. The fluid passes up and out of the upper outlet or opening 46, indicated by the

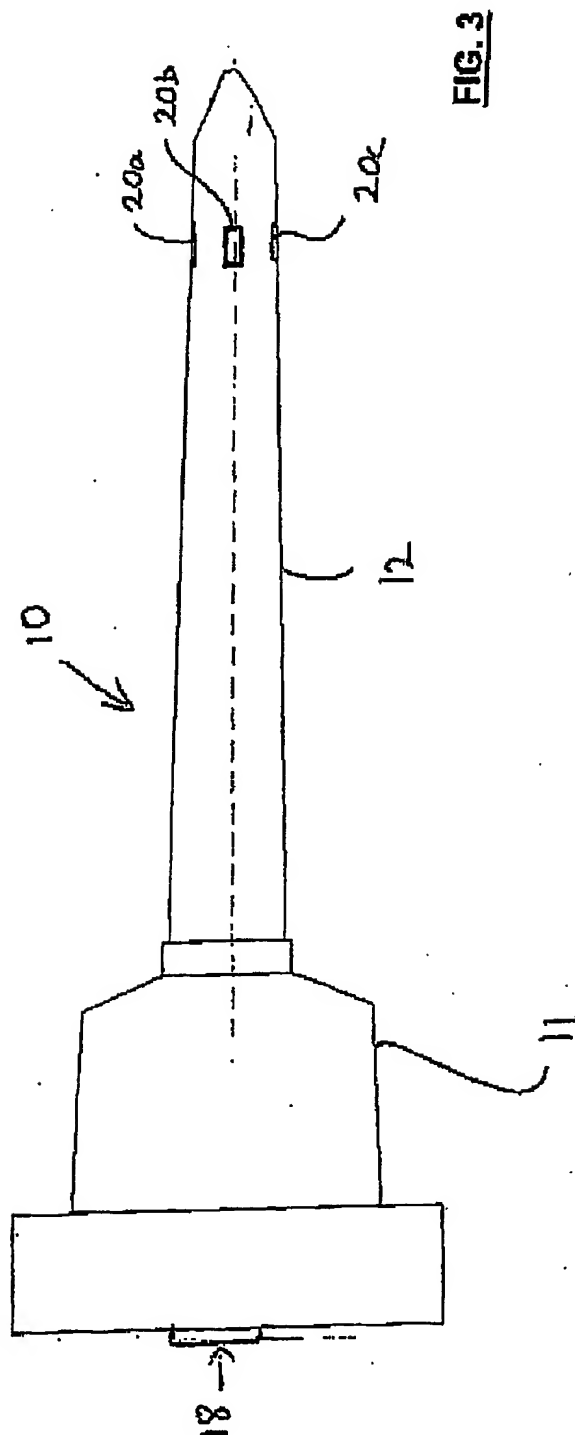
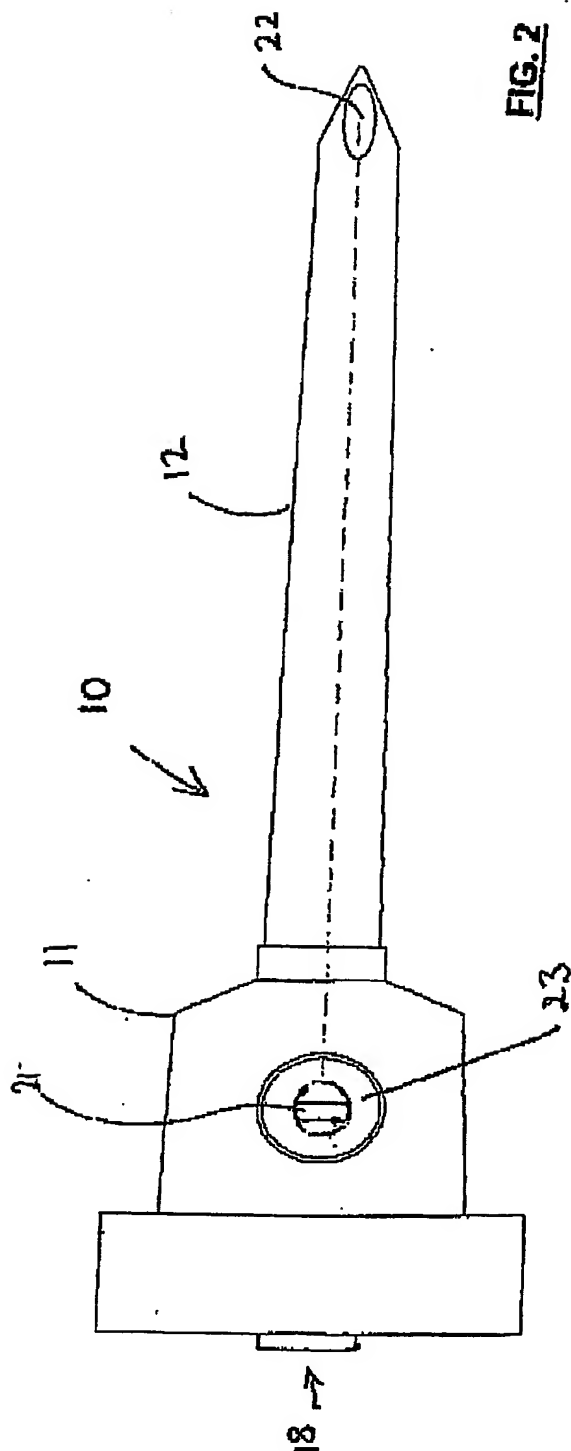
unbroken arrows in Figure 6. Fluid from the bag is still able to flow freely into the chamber 14 by means of the main channel 50 through openings 48, indicated by the broken arrows in Figure 6. The distancing of the main channel from the side channel ensures that the medication is sufficiently diluted in the fluid contained in the bag

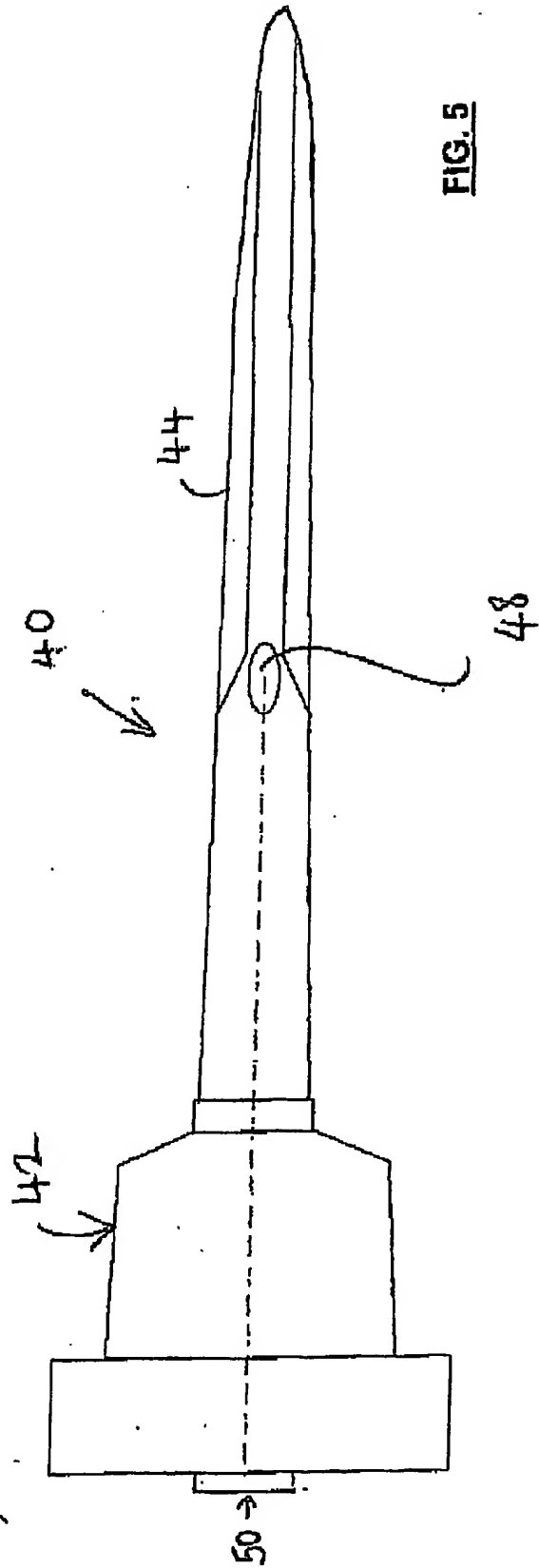
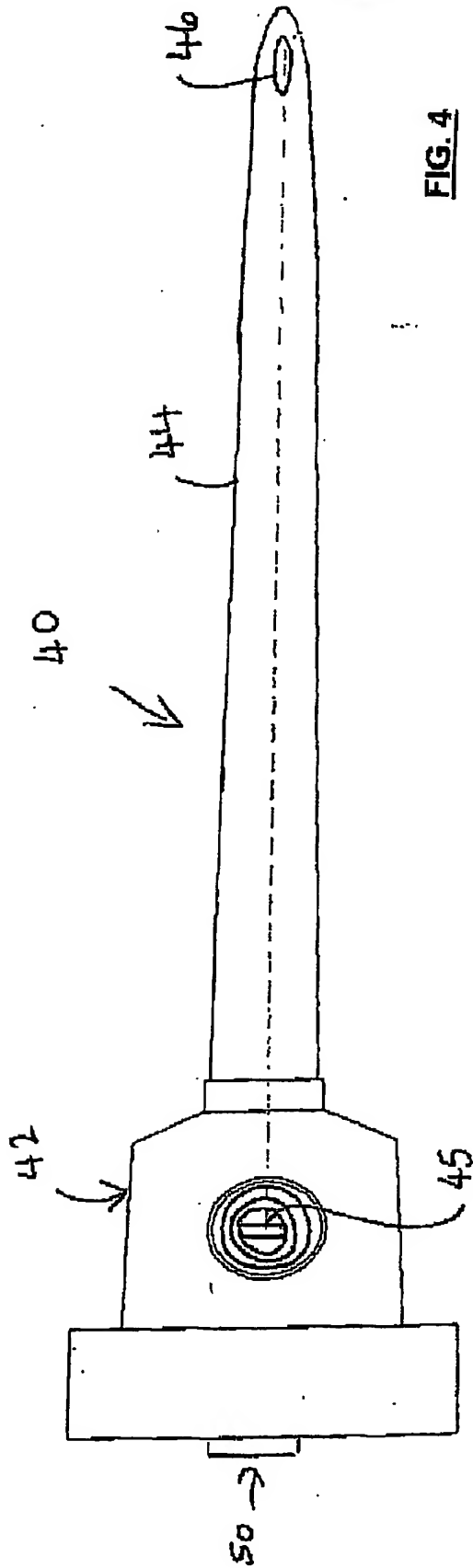
- 5 before being delivered to a patient via the chamber and line. If a conventional giving set head was used, the medication introduced via the air inlet would pass straight out of the bag through the giving set in an undiluted state.

The present invention removes the requirement for a needle to be attached to a syringe to enable a fluid medicament to be introduced into an IV bag. This should
10 assist in reducing the number of needlestick injuries suffered by medical staff and reduces the number of spent sharps that require disposal. Furthermore, it may also remove the need for the provision of additional site entry in the bag for receiving a needle. Mixing of the medicament with the fluid may also be enhanced since the medicament enters the bag at a higher level than the fluid exits the bag whereas with
15 conventional sets the medicament enters the bag on the same level as the fluid exits the bag. The air inlet, though adapted to receive a needleless syringe, is still able to operate as valve to allow entry of air, when required, by removal of the cover.



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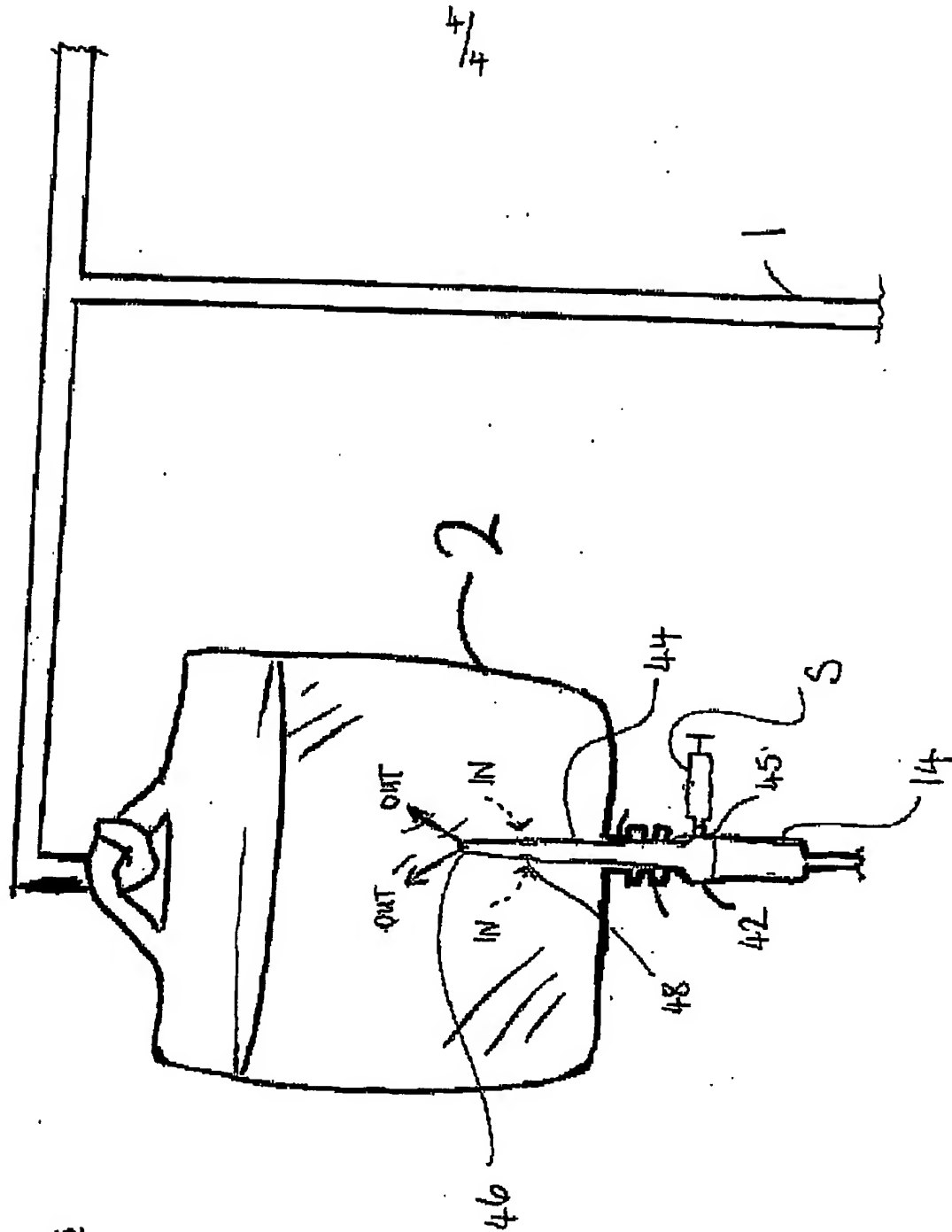


FIG. 6

PCT Application
GB0305348

